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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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04/09/2004

Michael John Dunkley

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NEKTAR THERAPEUTICS  
201 INDUSTRIAL ROAD  
SAN CARLOS, CA 94070

EXAMINER

ALI, SHUMAYA B

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/822,850	<b>Applicant(s)</b> DUNKLEY ET AL.	
	<b>Examiner</b> SHUMAYA B. ALI	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-9 and 11-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 12-18 is/are rejected.
- 7) ☒ Claim(s) 6-9 and 11 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. In response to the office action mailed on 12/13/07, Applicant amended claims 1 and 14 and cancelled claim 5. Currently claims 1-4, 6-9, 11-18 are pending in the instant application.

### ***Specification***

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d) (1) and MPEP § 608.01(o). Correction of the following is required: specification lacks proper antecedent basis for "the energy for aerosolization is supplied solely by the user" (see claim 1, lines 10 and 11).

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**4. Claims 1, 9, 12, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Steil US 3,918,451.**

As to claim 1, Steil discloses a handheld aerosolization apparatus comprising a housing defining a chamber (1) having a plurality of air inlets (4, plurality of air inlets 14, and slots 18), the chamber being sized to receive a capsule (11) which contains an aerosolizable

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pharmaceutical formulation (col.1 lines 8-10); a puncturing mechanism (12 (blade portions)) in the housing for creating one or more openings (13) in the capsule; a shield (12 (flat covering portion where pin portions are attached, see fig.1)) which covers inlets (18) but does not cover inlets (4 and 14), the shield comprises at least two covering portions (fig.1), each covering portion covering at least one inlet (18). Depending on how the user holds the inhaler the shield can prevent blockage of at least two air inlets (plurality of air inlets 14) by user grasping the apparatus; and an end section (17) associated with the housing, the end section sized and shaped to be received in a user's mouth or nose so that the user may inhale through the end section to aerosolize the pharmaceutical formulation and to inhale aerosolized pharmaceutical formulation that has exited the capsule (col.1 lines 20-25).

As to claim 9, Steil in figure 1 shows the shield extends longitudinally along the apparatus.

As to claim 12, Steil in figure 1 shows the chamber is elongated and the capsule is received lengthwise within the elongated chamber.

As to claim 13, airflow through the inlets (14) inherently allows a swirling airflow within the chamber (1) when the user breathes through the end section (17).

**5. Claims 1-4, 9, and 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Ohki et al. US 5,619,985.**

As to claim 1, Ohki discloses a handheld aerosolization apparatus (apparatus of fig.1 and 9) comprising a housing defining a chamber (6) having a plurality of air inlets (10A, 11A, 12, and 14), the chamber being sized to receive a capsule (16) which contains an aerosolizable

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pharmaceutical formulation; a puncturing mechanism (19) in the housing for creating one or more openings (fig.9) in the capsule; a shield (18) which covers inlets (10A, 11A) but does not cover inlets (12 and 14), the shield comprises at least two covering portions (fig.9), each covering portion covering at least one inlet (10A and 11A). Depending on how the user holds the inhaler the shield can prevent blockage of at least two air inlets (12 and 14) by user grasping the apparatus; and an end section (1,2, 3) associated with the housing, the end section sized and shaped to be received in a user's mouth (section 3) or nose so that the user may inhale through the end section to aerosolize the pharmaceutical formulation and to inhale aerosolized pharmaceutical formulation that has exited the capsule (col.10 lines 24-38).

As to claims 2 and 4, figure 9 of Ohki shows the shield is a part of the end section.

As to claim 3, figure 1 of Ohki shows the end section (1, 2, 3) is removably connected to the housing (6) and the end section (1, 2, 3) may be removed from the housing to provide access to the chamber (9).

As to claim 9, Ohki in figure 9 shows the shield extends longitudinally along the apparatus.

As to claim 12, Ohki in figure 9 shows the chamber is elongated and the capsule is received lengthwise within the elongated chamber.

As to claim 13, airflow through the inlets (12 and 14) inherently allows a swirling airflow within the chamber (9) when the user breathes through the end section (3).

**6. Claims 14, 15, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Gottenauer et al. US 5,881,719.**

As to claim 14, Gottenauer discloses a handheld aerosolization apparatus comprising a housing defining a chamber (interior space of the inhaler of figure 1) having a plurality of air inlets (12, 7, and 32), the chamber being sized to receive a capsule (31) which contains an aerosolizable pharmaceutical formulation (38); a puncturing mechanism (10) in the housing for creating one or more openings in the capsule; a shield (18) which covers a portion of but not all of at least one of the air inlets (shield 18 does not cover inlets 7 and 32, see fig.8); and an end section (1) associated with the housing, the end section sized and shaped to be received in a user's mouth so that the user may inhale through the end section to aerosolize the pharmaceutical formulation and to inhale aerosolized pharmaceutical formulation that has exited the capsule, and the energy for aerosolization is supplied solely by the user (see column 10 lines 1-6).

As to claim 15, figure 5 of Gottenauer shows the shield (18) is a portion of the end section (1).

As to claim 16, airflow through the inlets (32 and 7) inherently allows a swirling airflow within the chamber (interior space of the inhaler of figure 1) when the user breathes through the end section (1).

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gottenauer et al. US 5,881,719 in view of Gupte et al. US 5,685,294.

As to claim 16, Gottenauer lacks the end section is removably connected to the housing. However, Gupte teaches an inhalation apparatus with an end section (11) removably connected to a housing (10) via a hinge joint (12). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to connect one side of the shield (18) and the end piece (1) with a hinge joint (12) as taught by Gupte for easy access to the air inlets (12) for removing any powder clogging the inlets (12). Thus the modified Gottenauer's end section removably connects to the housing and "may be" removed from the housing to provide access to the chamber.

As to claim 17, figure 5 of Gottenauer shows the shield (18) is a portion of the end section (1). Thus the modified Gottenauer's shield is a portion of the end section.

***Response to Arguments***

10. Applicant's arguments with respect to claims 14-18 have been considered but are moot in view of the new ground(s) of rejection.

***Allowable Subject Matter***

11. The indicated allowability of claim 5 is withdrawn in view of the newly discovered reference(s) to Steil US 3,918,451.

12. Claims 6-8 and 11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHUMAYA B. ALI whose telephone number is (571)272-6088. The examiner can normally be reached on M-W-F 9 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shumaya B. Ali /  
Examiner, Art Unit 3771

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771